

Toxic Substance Control Act Risk-Based Notification for the Lincoln Park/Milwaukee River Channel Sediments Site, Milwaukee Estuary Area of Concern

PREPARED FOR: United States Environmental Protection Agency
Great Lakes National Program Office

PREPARED BY: CH2M HILL

DATE: January 18, 2011

1.0 Purpose and Scope

The Lincoln Park/Milwaukee River Channel Sediments Site (Lincoln Park/Milwaukee River Site) is located within the Milwaukee Estuary Area of Concern, in Milwaukee, Wisconsin. The site consists of Lincoln Creek downstream of Green Bay Road, the western oxbow of the Milwaukee River, and the Milwaukee River downstream of the confluence with Lincoln Creek to the Estabrook Park Dam. The Lincoln Park/Milwaukee River Site was divided into five zones during the Estabrook Impoundment sediment remediation predesign study (Wisconsin Department of Natural Resources, 2005). The zones consist of the following:

- Zone 1: Lincoln Creek from Green Bay Road to the confluence with the Milwaukee River
- Zone 2: Entire western oxbow in the Milwaukee River, which contains the main sediment deposit
- Zones 3, 4, and 5: Milwaukee River from the confluence of the western oxbow downstream to Estabrook Park Dam

The remedial design (Phase I) focuses on Zones 1, 2, and the northwestern part of Zone 3 (Zone 3a). Zones 4 and 5 and the remaining portion of Zone 3 will be addressed separately in the future. The Estabrook Park Dam forms the downstream boundary of the Lincoln Park/Milwaukee River Site, and backs up water approximately 2.5 miles to a point 0.3 mile upstream of Silver Spring Road on the Milwaukee River, creating a 103-acre impoundment. The dam also has an impact on Lincoln Creek to a point about 0.5 mile upstream of the confluence with the Milwaukee River. The dam was built on a limestone outcrop in the river channel in 1936 and has a hydraulic height of 8 feet and maximum storage of 700 acre-feet.

Sediment characterization conducted in the Lincoln Park/Milwaukee River Site in 2008 and 2009 identified sediments contaminated with polychlorinated biphenyls (PCBs) above the Toxic Substance Control Act (TSCA) level of concern of 50 parts per million or milligrams per kilogram (mg/kg) (CH2M HILL, 2009). Summary statistics for Aroclor concentrations measured in Zones 1 and 2 are presented in Table 1. Table A-4 in Attachment A presents the PCB data from the Great Lakes National Program Office (GLNPO) 2008 and 2009 sampling.

This memorandum presents the risk evaluation developed in cooperation with staff from United States Environmental Protection Agency's (USEPA's) GLNPO and the USEPA Region 5 TSCA Program to define PCB risk-based concentrations (RBCs) for sediment for the Lincoln Park/Milwaukee River Site that are protective of human health and the environment and are consistent with a risk-based cleanup approach, as required by the TSCA mega rule (Code of Federal Regulations 761.61[c]). The ultimate goal for the RBC calculation for sediment is to provide a range of target sediment cleanup levels for the Lincoln Park/Milwaukee River Site that will protect human and ecological health and will satisfy the TSCA risk-based cleanup requirements. The memorandum also summarizes the approaches and analysis used to identify RBCs for sediment to support TSCA notification required for cleanup of Lincoln Park/Milwaukee River Site sediments. A detailed presentation of the data is included as attachments to this technical memorandum.

2.0 Approach for Estimation of PCB Risk-Based Concentrations for Sediment

The estimation of RBCs for sediment (RBC_{sed}) follows the three-step process that is presented below.

1. **Estimation of biota-sediment accumulation factor (BSAF)** – A BSAF describes the empirical relationship between PCB concentrations in fish tissue and sediment, ideally co-located, where the sediment concentrations represent the source of contamination to the fish.
2. **Calculation of health-protective concentrations in fish (RBC_{fish})** – Concentrations of PCBs in fish tissues were calculated based on specified target risk levels protective of people or wildlife that consume these fish.
3. **Estimation of RBC_{sed} from RBC_{fish} and BSAF** – Using Steps 1 and 2, PCB RBCs in sediment were derived from acceptable concentrations of PCBs in fish (RBC_{fish}) and the relationship between PCBs in fish tissue and in sediment (BSAF).

3.0 Estimation of Biota-Sediment Accumulation Factor

For persistent bioaccumulative compounds like PCBs, significant exposure in humans and wildlife occurs through the uptake and accumulation of PCBs in food. At a site where the PCB contamination is in sediment, the primary route of human and wildlife exposure is through consumption of fish. In order to translate from concentrations in fish tissue to RBCs in sediment, an empirical relationship between the concentration of PCBs in fish and the concentration of PCBs in sediment, termed BSAF, is required. The BSAF is expressed as the following equation:

$$BSAF = \frac{\frac{Conc_{fish}}{lipid}}{\frac{Conc_{sed}}{TOC}}$$

where:

BSAF = Ratio of contaminant in biota to contaminant in sediment (unit-less)

Conc_{fish} = Concentration of PCBs in fish tissue, either whole-body or fillet, on a lipid normalized basis (mg/kg lipid)

Conc_{sed} = Concentration of PCBs in an organic carbon basis (mg/kg organic carbon)

Site-specific BSAFs are derived using site-specific fish tissue and sediment data. Where adequate site-specific data are unavailable, BSAFs may be derived from available literature. For the purposes of this evaluation, literature-based BSAFs were used because site-specific fish tissue PCB concentrations were not available.

For the RBCs, both a pelagic sport fish and bottom feeding species were considered relevant for the calculations. The BSAF database (USEPA, 2007) as well as a recent article by Burkhard et al. (2010) was consulted in selecting the appropriate BSAFs for the site.

Multiple BSAFs were pulled from the literature to reflect different types of fish eaten by humans and ecological receptors. Based on a review of site data, BSAFs were chosen for the following types of fish species:

- Sport fish/terminal predator – smallmouth bass (*Micropterus dolomieu*) or largemouth bass (*Micropterus salmoides*)
- Bottom feeder – brown bullhead (*Ameiurus nebulosus*) or white sucker (*Catostomus commersonii*)
- Forage fish

All BSAFs for sportfish and bottom feeders (fillet and whole body) in the USEPA BSAF database are presented in Table A-1 of Attachment A and are summarized in Table A-2, providing the distribution of the available BSAFs. Table A-3 presents a summary of the BSAFs for forage fish species relevant for ecological receptors.

Burkhard et al. (2010) evaluated scenarios in which BSAFs were applied from one location, species, and/or site to another location, species, and/or site using PCB BSAF information available in the USEPA BSAF data sets. The authors reported results for each BSAF comparison scenario for fish, mussels, and decapods. Relevant to questions about BSAFs at the Lincoln Park/Milwaukee River Site were PCB BSAF comparisons for fish of the same species and for fish of different species across locations (Superfund Sites).

Burkhard et al. did not present a specific quantitative formula for predicting BSAFs at one location from another; however, their results (Table 2) indicated (but were not limited to) the following:

- A ± 2.9 -fold range around a PCB BSAF determined for a given fish species at one Superfund Site captures approximately 50 percent of the true BSAFs for the same species at a different Superfund Site.
- A ± 10 -fold range around any BSAF (PCB, polychlorinated dibenzodioxin and dibenzofuran, polycyclic aromatic hydrocarbon, or chlorinated pesticide) determined for a given fish species at one Superfund Site will have approximately a 90 percent

probability of capturing the true BSAF for the same chemical and the same species at a different Superfund Site.

The findings were considered when selecting BSAFs for the Lincoln Park/Milwaukee River evaluation.

3.1 Human Health BSAFs

The USEPA BSAF database (USEPA 2007) was the primary literature source for applicable BSAFs. Additionally, BSAFs from other PCB-contaminated sites that reasonably matched the Lincoln Park/Milwaukee River Site in key factors such as habitat (such as, freshwater river), fish species samples, and sediment characteristics (such as, organic carbon content) were weighted more heavily in making final decisions on BSAFs selected.

Because few BSAFs based on PCBs in fish tissue fillets were available, BSAFs derived from both fillet and whole body fish tissues were considered for developing human health RBCs. Because the BSAF model uses lipid-normalized tissue concentrations, the primary source of variation (lipid content) between whole body and fillet PCB concentration is essentially accounted for in the BSAF model. Site-specific BSAFs determined using fillet tissue are generally within the same range as those determined using whole body tissue (Attachment A, Table A-1).

To find the most appropriate literature values, available site characteristics, specifically PCB concentrations and total organic carbon (TOC), were analyzed and are shown in Table 1, both by zone and for the entire site. The geometric mean sediment PCB concentration (normalized to TOC) for the entire Lincoln Park/Milwaukee River Site (Zones 1 and 2) was 42 mg/kg organic carbon (OC), and for Zone 2, where a large proportion of the fish may be found, was 57 mg/kg OC (Table 1). The mean TOC at Lincoln Park was 6.7 percent. Overall, the system and site contaminant characteristics at the Lincoln Park/Milwaukee River Site are similar to those at the Sheboygan River Site, nearby Great Lakes contaminated site also located along the western shore of Lake Michigan. The closest matching record (Attachment A, Table A-1) from the Sheboygan River Site had a PCB concentration of 70.4 mg/kg OC, 6 percent TOC, and a BSAF for smallmouth bass of 4.1. Overall, the Sheboygan River Site had a geometric mean sediment PCB concentration of 180 mg/kg OC, mean TOC of 3.5 percent, and BSAFs of 4.2 and 1.7 for smallmouth bass and white sucker, respectively.

Median BSAFs reported in the USEPA database were 2.0 and 1.1 for bass species and sucker/catfish species, respectively (Table A-2). Using the general results of Burkhard et al. (2010), bounds on median BSAFs reported in the USEPA database (USEPA 2007) were estimated for comparisons of BSAF for similar species across sites (Attachment A, Table A-2). Using this information combined with the assumption that the similarity of Sheboygan River can be used to limit uncertainty in the BSAF estimate for the Lincoln Park/Milwaukee River Site, BSAFs selected for human health RBC_{fish} were 4 and 1.7 for sportfish and bottom feeders, respectively (Table 3).

3.2 Ecological Health BSAFs

To derive BSAFs for modeling RBCs for ecological receptors, an approach similar to that used for human health BSAFs was used. The sportfish species (bass) for which BSAFs were

used to develop human health RBCs also represent terminal fish predators to be evaluated for ecological health. For consistency, the same BSAF of 4.0 that was used to develop human health RBCs was used to develop RBCs for ecological health.

To derive RBCs for fish-eating wildlife such as the belted kingfisher (*Megaceryle alcyon*) and mink (*Neovison vison*), an average BSAF representing small fish typical of those serving as forage for wildlife was selected (see supporting data in Attachment A, Table A-3). The USEPA BSAF database (USEPA, 2007) was searched for BSAFs for small fish species and/or young-of-year fish, and the median BSAF of 5.4 was selected (Table 3).

4.0 Derivation of Human Health RBC in Fish

Human-health-based RBCs in fish (RBC_{fish}) were derived using approaches and assumptions consistent with USEPA risk assessment guidance (USEPA, 1989; USEPA, 1991a) and procedures for developing Great Lakes Sport Fish Consumption Advisory (Anderson et al., 1993) and were developed in coordination with GLNPO and TSCA.

4.1 Exposure Assessment

Two exposure scenarios were considered for the RBC_{fish} calculations. An upper-bound exposure scenario was used to estimate a reasonable maximum exposure (RME) of recreational fish consumption (again using the guidance and direction cited above). The intent of doing an RME scenario was to develop a higher yet still possible exposure estimate. To assess a more average scenario of recreational sport fishing, this assessment also uses a central tendency exposure (CTE) estimate of fish consumption. The CTE case reflects exposure conditions that are more likely to be associated with the average person and was developed using the above guidance and direction that is appropriate for Great Lakes fishers.

The exposure parameters used for generating RME and CTE risk estimates for fish consumption are as listed in Table 4. Some of the exposure factors, such as body weight and exposure duration, are standard default values from USEPA guidance documents.

Recreational anglers are the populations potentially exposed by ingestion of fish from the Lincoln Park/Milwaukee River Site. For evaluation of the recreational angler scenario, the fish diet was assumed to comprise fillets from either sportfish such as smallmouth and largemouth bass or bottom feeders such as suckers and catfish. The bass species are top-level predators representing species with high-end bioaccumulation due to their position in the food web and are commonly harvested by anglers. The bottom feeders are good indicators for PCBs because of their greater lipid content and feeding habits (bottom feeder). This approach is intended to address the potential for higher exposures by certain ethnic communities or other individuals who might consume bottom-feeder fish.

Fish consumption is expressed in terms of an annualized ingestion rate, in units of grams per day. For the RME case, the ingestion rate of 38.7 grams per day is based on the 95th percentile consumption rate of recreationally caught fish, from the West et al. study (1989, as cited in USEPA, 1997a) from the sport anglers fish consumption surveys conducted in Michigan. For the CTE case, the ingestion rate of 10.9 grams per day is based on the 50th percentile consumption rate from the West et al. study (1989). For the purpose of providing

a protective estimate for this evaluation, it is assumed that all (100 percent) of an exposed individual's fish diet comes from recreationally caught fish from this stretch of river. The ingestion rates used are specifically for recreationally caught fish, and do not include other sources, such as market- or restaurant-purchased fish (USEPA, 1997a).

Losses of PCBs during cleaning and cooking of fish were assumed to be 50 percent based on studies reported in the literature for this chemical class (Zabik, 1995). The losses occur during removal of skin and fat, draining of fluids during cooking, and/or dripping of oils during grilling. The amount of cooking/cleaning loss is consistent with the *Protocol for a Uniform Great Lakes Sports Fish Consumption Advisory* (Anderson et al., 1993).

4.2 Toxicity Assessment

PCBs are capable of eliciting both noncarcinogenic toxic effects and cancer (carcinogenic) effects. The health risks for noncarcinogenic and carcinogenic effects were calculated separately based on different toxicity values.

The toxicity value describing the dose-response relationship for noncancer effects is the reference dose value expressed in units of milligrams per kilogram bodyweight per day (mg/kg-day). The chronic oral reference dose value of 0.00002 mg/kg-day PCBs, based on immunotoxic effects, was selected from USEPA's Integrated Risk Information System (IRIS), an electronic database available through the USEPA National Center for Environmental Assessment in Cincinnati, Ohio.

The toxicity value for cancer effects is expressed as a cancer slope factor that converts estimated intake directly to excess lifetime cancer risk. Slope factors are expressed in units of risk per level of exposure (mg/kg-d). The toxicity values (cancer slope factors and RfDs) used in this evaluation were obtained from the IRIS database (USEPA, 2010). The IRIS database, prepared and maintained by USEPA, contains health risk and USEPA regulatory information on specific chemicals. USEPA has classified PCBs as a probable human carcinogen (Group B2) (USEPA, 1999). The cancer slope factor is 2.0 mg/kg-d from the USEPA IRIS database.

Fish tissue PCB RBCs were calculated to account for both noncarcinogenic health effects and carcinogenicity. For the noncarcinogenic endpoint associated with PCBs, a target hazard quotient (HQ) of 1.0 is used to calculate RBCs in fish tissue. For the carcinogenic endpoint, fish tissue concentrations corresponding to excess lifetime cancer risk levels of 1×10^{-6} , 1×10^{-5} , and 1×10^{-4} are calculated to span the risk range USEPA generally uses to make risk-management decisions (USEPA, 1991b). Table 4 presents the calculated fish tissue RBCs as well as the corresponding exposure assumptions used for the two exposure scenarios.

4.3 Human Health Risk-Based Cleanup Goals (RBC_{sed})

Human health RBCs for sediment were derived using the BSAF estimates for sportfish (bass species) (BSAF = 4.0) and the bottom feeders (sucker and catfish species) (BSAF = 1.7) (see Table 4 for RBC_{fish} calculations), and were combined using the equation provided in Table 5.

The calculated sediment RBCs correspond to each of the fish tissue RBCs for the recreational angler (CTE and RME) scenarios, for both sportfish and bottom feeder consumption (Table 5).

Sportfish: To be protective of the cancer following sportfish consumption, the estimated sediment PCB cleanup levels corresponding to cancer risks of 1×10^{-6} , 1×10^{-5} , and 1×10^{-4}

range from 0.011 to 1.1 mg/kg dry weight (dw) for the RME case, and from 0.037 to 3.7 mg/kg dw for the CTE case. For the noncarcinogenic endpoint, the estimated sediment PCB cleanup levels corresponding to an HQ of 1 range from 0.18 mg/kg dw for the RME case to 0.64 mg/kg dw for the CTE case.

Bottom Feeders: To be protective of cancer following consumption of bottom feeders, the estimated sediment PCB cleanup levels corresponding to the risk levels of 1×10^{-6} , 1×10^{-5} , and 1×10^{-4} , range from 0.010 to 1.0 mg/kg dw for the RME case, and from 0.036 to 3.6 mg/kg for the CTE case. For the noncarcinogenic endpoint, the estimated sediment PCB cleanup levels corresponding to an HQ of 1 range from 0.17 mg/kg dw for the RME case to 0.61 mg/kg dw for the CTE case.

5.0 Ecological Health Risk-Based Cleanup Goals

Ecological health-based RBCs were derived using approaches and assumptions consistent with USEPA risk assessment guidance (USEPA, 1992; USEPA, 1997b; USEPA, 1998).

5.1 Exposure Assessment

Derivation of risk-based PCB cleanup goals protective of ecological health focused on the following ecological pathways:

- Fish—exposure by direct uptake from sediment and food.
- Wildlife (for example, birds and mammals)—exposure by direct uptake from sediment and food.

To streamline the process, GLNPO and TSCA staff agreed to focus on the following receptors as representative of these pathways:

- Smallmouth bass, a terminal predator
- Belted kingfisher, a fish-eating bird
- Mink, a fish-eating mammal

The exposure parameters used to calculate RBCs in fish are presented in Table 6.

5.2 Toxicity Assessment

Toxicity reference values (TRVs) for fish, birds, and mammals were taken from the literature. Attachment B presents a review of the literature used to select TRVs. A range of toxicity studies was selected that measured the effects of PCBs on survival, growth, and reproduction. The TRVs were no observed effect concentrations (NOECs) and lowest observed effect concentrations (LOECs) for fish, and no observed adverse effect levels (NOAELs) and lowest observed adverse effect levels (LOAELs) for birds and mammals. Potential TRVs for smallmouth bass, belted kingfisher, and mink were used to calculate the 25th and 50th percentiles of the distribution. The use of the 25th and 50th percentiles and the NOEC/NOAEL and LOEC/LOAEL provide a range of conditions that bound the reasonable uncertainty in the effects data. Tables B-1, B-2, and B-3 in Attachment B summarize the data and highlight the selected 25th and 50th percentile values. The TRVs used to calculate RBCs are presented in Table 6.

5.3 Calculation of RBCs

Ecological health RBCs along with the equations and parameters used to calculate them are presented in Table 6. For the protection of fish, the RBCs based on NOECs ranged from 7.5 to 16 mg/kg dw total PCBs for the 25th percentile and median TRVs, respectively. RBCs based on LOECs ranged from 13 to 53 mg/kg dw total PCBs. For the protection of fish-eating birds, the RBCs based on NOAELs ranged from 0.047 to 0.22 mg/kg dw total PCBs for the 25th percentile and median TRVs, respectively. RBCs based on LOEALs ranged from 0.47 to 1.2 mg/kg dw total PCBs. For the protection of fish-eating mammals RBCs based on NOAELs ranged from 0.40 to 0.81 mg/kg dw total PCBs for the 25th percentile and median TRVs, respectively. RBCs based on LOAELs ranged from 0.40 to 0.99 mg/kg dw total PCBs.

6.0 Summary

A range of risk-based total PCB sediment concentrations were developed that are protective of human health and ecological health (Table 7). The range of concentrations captures various exposure scenarios in the Lincoln Park/Milwaukee River site (for example, recreational angler vs. special populations) and the uncertainty in the underlying knowledge of the effects of PCBs on ecological resources. The RBCs identified in this technical memorandum will provide a range of target sediment cleanup levels that will achieve the remedial action objective of protection of human and ecological health and satisfy the TSCA risk-based cleanup requirements.

7.0 Works Cited

- Anderson, H. A., J. F. Amhrein, P. Shubat, and J. Hesse. 1993. *Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory*. Great Lakes Fish Advisory Task Force Protocol Drafting Committee. September.
- Burkhard, L. P., P. M. Cook, and M. T. Lukasewycz. 2010. *Environmental Toxicology and Chemistry* 29(1): 230-236.
- CH2M HILL. 2009. *Feasibility Study Report, Lincoln Park/Milwaukee River Channel Sediments Site, Milwaukee Estuary Area of Concern*. December.
- Nagy, K. A. 2001. "Food Requirements of Wild Animals: Predictive Equations for Free-Living Mammals, Reptiles, and Birds." *Nutrition Abstracts and Reviews Series B: Livestock Feeds and Feeding*. Vol. 71, No. 10.
- Skinner, L. C., B. Trometer, A. J. Gudlewski. 2009. *Data Report for Residues of Organic Chemicals and Four Metals in Edible tissues and Whole Fish for Fish Taken from the Buffalo River, New York*.
- U.S. Environmental Protection Agency (USEPA). 1989. *Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A), Interim Final (RAGS)*. EPA/540-1-89/002. OSWER Directive 9285.701A. Environmental Protection Agency, Office of Solid Waste and Emergency Response. Washington, DC.

USEPA. 1991a. *Human Health Evaluation Manual, Part B: Development of Risk-based Preliminary Remedial Goals*. Office of Solid Waste and Emergency Response. OSWER Directive 9285.7-01B. December 13.

USEPA. 1991b. *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*. OSWER Directive 9355.0-30, April 22.

USEPA. 1992. *Framework for Ecological Risk Assessment*. EPA/630/R-92/001.

USEPA. 1993. *Wildlife Exposure Factors Handbook*. Volume I of II. EPA/600/R-93/187a.

USEPA. 1997a. *Exposure Factors Handbook*. Office of Research and Development. EPA/600/P-95/002Fa,b,c. August.

USEPA. 1997b. *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments*. Interim Final. EPA/540/R-97/006.

USEPA. 1998. *Guidelines for Ecological Risk Assessment*. EPA/630/R-95/002F.U.S.

USEPA. 1999. *Polychlorinated Biphenyls (PCBs) Update: Impact on Fish Advisories*. EPA/823/F-99/019.

USEPA. 2007. BSAF (Biota-Sediment Accumulation Factor) Data Set – Version 1.0. Office of Research and Development, National Health and Environmental Research Laboratory. Mid-Continent Ecology Division, Duluth, MN. Available:
http://www.epa.gov/med/prods_pubs.htm.

USEPA. 2010. Integrated Risk Information System (IRIS) [Online]
<http://www.epa.gov/iris/>.

West, P. C., M. J. Fly, R. Marans, and F. Larkin. 1989. Michigan Sport Anglers Fish Consumption Survey. Technical Report #1. Prepared for Michigan Toxic Substance Control Commission. Natural Resources Sociology Research Lab.

Zabik, M. E., M. J. Zabik, A. M. Booren, M. Nettles, J. H. Song, R. Welch and H. Humphrey. 1995. *Pesticides and Total Polychlorinated Biphenyls In Chinook Salmon and Carp Harvested from The Great Lakes: Effects Of Skin-On and Skinoff Processing and Selected Cooking Methods*. J. Agric. Food Chem. 43:993-1001.

Attachment A
Data Used in Assessment

Attachment B
Ecological Toxicity Reference Values
Literature Review

Ecological Toxicity Reference Values Literature Review

Fish Toxicity Reference Values

Toxicity studies that relate polychlorinated biphenyls (PCBs) in fish tissue to adverse effects were identified from a search of electronic databases and reference sources, including the following:

- Environmental Residue-Effects Database (2003)
- ECOTOX Database (United States Environmental Protection Agency [USEPA], 2003)
- Jarvinen and Ankley (1999), a compilation of tissue residue no observed effect concentrations (NOECs) and lowest observed effect concentrations (LOECs)
- Scientific literature searches through search engines such as BIOSIS and Science Direct

Databases were searched for fish dose-response studies in which tissue concentrations were measured.

Studies were selected for review if whole-body tissue concentrations and measured survival, growth, or reproductive effects data were available. Studies reporting residue concentrations in tissues other than whole-body (for example, egg or other organ tissues) were reviewed when relevant endpoints were measured. All life stages, including eggs, were considered. Fish-egg tissue residue toxicity reference values (TRVs) were converted into adult whole-body tissue residue TRVs using conversion factors reported in literature.

The acceptability of fish toxicity studies was determined through best professional judgment, taking into account the following:

- Was the observed toxicity a result of a single constituent? Studies using field-collected fish with background constituent concentrations in tissue cannot attribute toxicity to one specific constituent unless there is strong evidence that all other constituents in the tissue are below toxic levels.
- What is the ecological relevance of the exposure duration? Chronic studies measuring exposure for 30 days or longer were preferred.
- Did the measured endpoint in the study directly measure the growth, survival, or reproductive success of the test organism?

PCB Aroclors

For PCBs (as Aroclors), the proposed TRVs are derived from NOECs and LOECs for the individual Aroclor mixture with the highest toxicity for comparison with total PCB

concentrations (sum of Aroclors). Twenty papers on the potential adverse effects of PCB mixtures on fish were reviewed. Details of the studies are summarized in Table B-1. The potential mechanisms of exposure included dietary ingestion, water exposure, gavage, and maternal transfer. Concentrations in whole-body tissue were reported in 16 reviewed studies (Duke et al., 1970; Fisher et al., 1994; Hansen et al., 1971, 1973, 1974, 1975; Hattula and Karlog, 1972; Hendricks et al., 1981; Lieb et al., 1974; Matta et al., 2001; Mauck et al., 1978; Mayer et al., 1977, 1985; Nebeker et al., 1974; Powell et al., 2003), and egg tissue concentrations were reported in four reviewed studies (Fisher et al., 1994; Freeman and Idler, 1975; Mac and Seelye, 1981; McCarthy et al., 2003).

Adverse effects on growth, mortality, reproduction, and behavior were reported in both laboratory-raised and field-collected fish. Five additional studies measuring the toxicity of PCBs to fish were reviewed; however, the studies were excluded from the TRV selection process because they did not meet the criteria used for TRV literature selection. Specifically, studies in which no toxic effects were reported (Kuehl et al., 1987) were excluded from the TRV selection process. In addition, studies that reported endpoints that were not related to growth, mortality, reproduction, and behavior, such as enzymatic activity, were not included in the TRV selection process (Melancon and Lech, 1983). DeFoe et al. (1978) was not included in the TRV selection process because no tissue concentrations were reported at a time when effects were observed. Finally, Rhodes and Casillas (1985) was excluded from the TRV selection process because fish were exposed to a mixture of constituents in the laboratory.

Several studies were evaluated to derive conversion factors between egg tissue residues and maternal adult tissue residues. Three papers that report PCB concentrations in maternal adults relative to eggs were identified (Miller, 1993; Niimi, 1983; Russell et al., 1999). Russell et al. (1999), and Miller (1993) report only egg and maternal adult fillet data, which is not directly usable to derive a whole-body concentration for comparison with site-specific fish data; therefore, PCB egg to adult conversion factors were based on data from Niimi (1983). Niimi (1983) reports whole-body maternal adult (with eggs) and unfertilized egg constituent concentration data for PCBs (quantified using a 4:1 Aroclor-1254:1260 analytical standard) from rainbow trout, white sucker, white bass, smallmouth bass, and yellow perch collected from Lake Ontario and Lake Erie. Niimi (1983) notes that the constituent concentrations in fertilized eggs would be two to three times lower than those reported for unfertilized eggs because of water uptake prior to egg hardening. Therefore, because available egg TRV papers report fertilized egg data, to derive egg-adult conversion factors, egg concentration data reported in Niimi (1983) were conservatively divided by two to approximate fertilized egg concentrations. Because Niimi (1983) showed that the ratio of constituents in eggs to constituents in maternal adults was dependent on species, species-specific (that is, salmonids and trout species) egg-to-adult conversions were used if a species was the same or closely related to one of the species reported in Niimi (1983) (that is, rainbow trout). If no species-specific conversion was available, an average egg-to-adult conversion across the five species (that is, rainbow trout, white sucker, white bass, smallmouth bass, and yellow perch) reported in Niimi (1983) was used (list value).

Table B-1 presents the fish PCB effects concentrations reported in the reviewed studies. Whole-body tissue residues of PCBs in nine species (rainbow trout, brook trout, Atlantic salmon, sheepshead minnow, lake trout, spot, pinfish, goldfish, and coho salmon) were

associated with adverse effects on growth, survival, behavior, or reproduction in 16 of the reviewed studies. Whole-body tissue residue LOECs ranged from 1.53 mg/kg for fry mortality of field-collected brook trout (Berlin et al., 1981) to 645 milligrams per kilogram on wet-weight basis (mg/kg ww) for growth and mortality of fingerling coho salmon (Mayer et al., 1977). In the study reporting the lowest LOEC (Berlin et al., 1981), field-collected eggs were exposed to three levels of PCB concentrations via diet and water for 176 days, and fry mortality was observed at all exposure levels. The concentration in fry tissue exposed to the lowest level was 1.53 mg/kg ww PCBs after 176 days of exposure (Berlin et al., 1981); however, the field-collected eggs contained 7.6 mg/kg ww PCB and 4.7 mg/kg ww dichlorodiphenylethylene (DDE), and possibly other, uncharacterized organic constituents that could have contributed to the reported toxicity. The next lowest LOEC was based on Fisher et al. (1994), in which live fry body weight was significantly reduced in Atlantic salmon following egg exposure to a PCB Aroclor mixture in water for 48 hours. The reported egg concentration of 1.53 mg/kg ww PCBs was converted into an adult tissue whole-body concentration of 7.2 mg/kg ww using a conversion factor of 4.69 (Niimi, 1983).

Whole-body tissue residue NOECs ranged from 0.98 mg/kg ww for growth of juvenile Chinook salmon (Powell et al., 2003) to 120 mg/kg ww for growth of rainbow trout (Mayer et al. 1985). Only the lowest NOEC of 0.98 mg/kg ww was below the lowest LOEC. In this study, Powell et al. (2003) measured no effect on juvenile Chinook salmon growth where whole-body tissue residues ranged from 0.74 to 0.98 mg/kg following 4 weeks of exposure to Aroclor 1254 in water.

Wildlife TRVs

Studies that relate dietary concentrations or bird egg concentrations of PCBs to adverse effects in wildlife were identified from a search of electronic databases and from a review of original studies identified in the following review sources:

- Agency for Toxic Substances and Disease Registry (ATSDR)
- ECOTOX database (USEPA electronic database)
- BIOSIS electronic database
- TOXNET database (National Library of Medicine)
- IRIS database (USEPA electronic database)
- U.S. Fish and Wildlife Service (USFWS) Contaminant Review Series electronic database
- Oak Ridge National Laboratory database (Sample et al., 1996)

For wildlife, only those studies in which relevant survival, growth, and reproduction were measured were reviewed. Selecting NOAELs and LOAELs based on the available reviewed literature were prioritized using the following guidelines:

- The preferred exposure duration was subchronic or chronic, or conducted during a critical life stage such as reproduction, gestation, or development. Acute studies were considered but not preferred.
- Only studies with mortality, growth, and/or reproductive effect endpoints were used for birds and mammals.

- Doses received by food ingestion were preferred over administration of the dose using drinking water, gavage, oral intubation, or injection because the non-dietary exposure route cannot be directly related to environmental exposure to the bird or mammal. Drinking water studies may overestimate dietary risk because gastrointestinal absorption may be higher for constituents ingested by drinking water (Sample et al., 1996). In some cases, however, TRVs based on studies with doses administered by injection, oral intubation, gavage, or drinking water were selected because no other studies are available.
- Preferred TRVs were based on results that were evaluated statistically to identify significant differences from control values. Studies were not considered if negative control groups were not included.
- In general, laboratory studies were preferred to studies using field-collected prey because controlled test conditions provide greater certainty that the observed response can be related to the constituent dose. The presence of multiple constituents and other environmental factors may result in adverse effects that complicate the interpretation of field study results (USEPA, 2003).

For the site-specific dietary TRVs, a daily dose is expressed as mg/kg body weight per day (mg/kg bw/d). Most studies reported toxicity results as the constituent concentration in food associated with adverse effects, although some presented results as a daily dose. The daily exposure dose was derived from a food concentration using the animal's body weight (kilograms) and ingestion rate (kilograms per day [kg/d]) as reported in the study or using values published elsewhere.

Avian TRVs

PCB Aroclors

Oral toxicity of PCB Aroclors to birds by food or capsule ingestion was evaluated in 21 studies (Ahmed et al., 1978; McLane and Hughes, 1980; Lowe and Stendell, 1991; Britton and Huston, 1973; Scott et al., 1975; Cecil et al., 1974; Peakall et al., 1972; Peakall and Peakall, 1973; Dahlgren et al., 1972; Tori and Peterle, 1983; Hill and Shaffner, 1976; Custer and Heinz, 1980; Platonow and Reinhart, 1973; Risebrough and Anderson, 1975; Fernie et al., 2000, 2001; Fisher et al., 2001; Bird et al., 1983; Haseltine and Prouty, 1980; Kreitzer and Heinz, 1974; Stickel et al., 1984).

In the studies reviewed, reproduction (measuring endpoints such as adult fertility, hatchability, eggshell thickness, egg production, eggshell weight, embryo development, courtship behavior, onset of nest initiation, clutch size, and embryo mortality and viability), avoidance behavior, adult growth, and mortality were observed in seven bird species exposed orally to PCB Aroclor mixtures. These endpoints were measured in the following bird species: American kestrels, chickens, turtle doves, mourning doves, pheasants, Japanese quail, mallard ducks, common gackles, red-winged blackbirds, brown-headed cowbirds, and starlings. Table B-2 summarizes the NOAELs and LOAELs derived from the dietary PCB studies reviewed. LOAELs ranged from 0.46 mg/kg bw/d for reproduction of American kestrels (Lowe and Stendell, 1991) to 34.4 mg/kg bw/d for avoidance behavior of Japanese quail (Kreitzer and Heinz, 1974). The lowest calculated LOAEL of all studies

reviewed was based on eggshell weight and thickness in American kestrels fed 0.46 mg/kg bw/d Aroclor-1248 (Lowe and Stendell, 1991). However, Lowe and Stendell (1991) did not report the overall effect of eggshell thinning on reproductive success (for example, hatchability, offspring viability) or the critical degree at which eggshell thinning would affect reproductive success (eggshell thickness of the experimental group was 5 percent different from the control). The next lowest LOAELs were reported in Britton and Huston (1973), who reported reduced hatchability in chickens fed 0.58 mg/kg bw/d PCBs Aroclor-1242 following 6 weeks of dietary exposure.

NOAELs ranged from 0.061 mg/kg bw/d for reproduction (i.e., egg production, and hatchability) of chickens (Scott et al., 1975) to 3.9 mg/kg bw/d for reproduction (egg production and eggshell thinning) of mallards (Risebrough and Anderson, 1975). NOAELs below the lowest LOAEL of 0.50 mg/kg bw/d were reported in four studies based on reproduction and ranged from 0.061 to 0.41 mg/kg bw/d (Scott et al., 1975; Platonow and Reinhart, 1973; Britton and Huston, 1973; McLane and Hughes, 1980). At the highest NOEC of 0.41 mg/kg bw/d, no effects on eggshell thickness, egg production, hatching success, and fledging success were reported in screech owls exposed to dietary PCBs for two generations (McLane and Hughes, 1980).

Mammal Toxicity Reference Values

PCB Aroclors

Fourteen papers on the potential adverse effects of PCBs on mammals were reviewed (Aulerich and Ringer, 1977; Aulerich et al., 1985, 1986; Bleavins et al., 1980; Brunström et al., 2001; Harris et al., 1993; Heaton et al., 1995; Hornshaw et al., 1983; Jensen et al., 1977; Kihlstrom et al., 1992; Restum et al., 1998; Ringer, 1983; Tillitt et al., 1996; Wren et al., 1987). The potential mechanism of exposure included dietary ingestion of laboratory or exposed field-collected diets. The most comprehensive studies of PCB toxicity in a wildlife mammalian species have been conducted with mink, and only mink studies were reviewed for PCBs. Mink also appears to be one of the most sensitive mammalian species tested (Fuller and Hobson, 1986) and, therefore, is considered a good surrogate for assessing risk to other mammals. Four additional studies on the toxicity of PCBs to mink or ferret were reviewed; however, these studies were excluded from the TRV selection process because they did not meet the TRV literature selection criteria. Specifically, studies in which no toxic effects were measured (Bleavins et al., 1984; Henny et al., 1981) or in which no dietary dose was reported (O'Shea et al., 1981) were not included in the TRV selection process. Studies that reported endpoints that were not related to growth, mortality, reproduction, and behavior (that is, hematology and liver pathology) were not included in the TRV selection process (Heaton et al., 1995). In addition, Platonow and Karstad (1973) was excluded from the TRV selection process because no data were presented in the paper and no true controls were used.

Table B-3 presents all of the NOAELs and LOAELs calculated for PCBs from the literature reviewed. Adverse effects on maternal growth, kit growth, kit survival, gestation length, whelping success, and reproductive failure were measured in mink following exposure to PCBs. LOAELs ranged from 0.037 mg/kg bw/d for reproduction in mink (Restum et al.,

1998) to 2,000 mg/kg bw/d for growth of mink (Harris et al., 1993). NOAELs ranged from 0.070 mg/kg bw/d for reproduction in mink (Hornshaw et al., 1983) to 480 mg/kg bw/d for growth of mink (Harris et al., 1993). The lowest LOAELs, ranging from 0.037 to 0.077 mg/kg bw/d PCBs, were reported in studies in which adverse reproductive effects (including reduced kit body weight, delay in the onset of estrus, and reduced whelping success) were observed in mink fed field-collected carp from the Great Lakes region over a chronic period (Restum et al., 1988; Hornshaw et al., 1983). In the studies, mink were fed a prepared diet containing various percentages of field-collected fish; thus, these studies only have quantitative relevance to mink exposed to constituent mixtures similar those found in the Great Lakes fish. In addition, there is uncertainty associated with these LOAELs because the field-collected fish contained other organic constituents (such as dioxins, DDE, dichlorodiphenyldichloroethane, chlordane) that likely could have contributed to the reproductive toxicity reported in mink. The next lowest LOAEL of 0.089 mg/kg bw/d was reported in Brunström et al. (2001) in which offspring growth was reduced in mink fed a Clophen A50 PCB mixture for 18 months.